

## REMARKS

Applicant respectfully requests reconsideration of this application in view of the foregoing amendments and the following remarks.

### A. Introductory Remarks

Upon entry of the foregoing amendments, claims 1-22 will be pending in the application. Claim 1 is presently being amended. Claims 13-22 are presently being added. No claims presently are being canceled.

None of the amendments or new claims introduce matter into the application. Exemplary support for the amendments to claim 1 exist in paragraphs 0018-0019 of the specification. Exemplary support for new claims 13-22 exists in paragraphs 0018-0091 of the specification, paragraphs 0066-0067 of the specification, and throughout the original claims.

### B. The Claims are "Complete"

Claims 1-12 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being "incomplete" for omitting essential elements. In particular, the Office asserted that omitted elements are (a) the condition being treated and (b) the result of treatment. Applicant traverses the rejection.

Contrary to the rejection, the claims recite all the essential elements for a method of treatment: administering 4-hydroxy tamoxifen percutaneously to a patient having dense breast tissue. Nonetheless, to clarify the purpose and result of the method, Applicant has amended the claims to recite that a patient having class III or class IV dense breast composition is treated for the purpose of reducing breast density. Accordingly, the rejection is moot and Applicant requests its withdrawal.

### C. The Claims Are Patentable over U.S. Patent No. 4,919,937 (Mauvais-Jarvis)

Claims 1-12 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. patent No. 4,919,937 ("Mauvais-Jarvis"). According to the Office, Mauvais-Jarvis teaches a method of treating breast conditions by percutaneously administering an aqueous alcoholic gel comprising trans-4-hydroxy tamoxifen. The breast conditions are said to include "benign cancerous affections." Applicant traverses the rejection.

Contrary to the rejection, Mauvais-Jarvis neither teaches nor suggests a method of reducing class III or class IV dense breast composition. The reference lacks any indication that percutaneously administered 4-hydroxy tamoxifen reduces breast density. Its vague suggestions that percutaneously administered 4-hydroxy tamoxifen can be used for treating “breast affections” (see abstract) lacks the specificity to either anticipate or render obvious the claimed invention. Mauvais-Jarvis not only fails to define “breast affections,” but entirely confuses the meaning of that term with further reference to “benign cancerous affections of the breast” (see abstract). Because “benign” and “cancerous” are mutually exclusive terms, the recommendation to treat “benign cancerous affections” is oxymoronic.

Even if one understood Mauvais-Jarvis as advocating the treatment of breast conditions generally, the reference does not specifically teach or suggest reducing class III or class IV breast density. There is no indication that the reference contemplates dense breast tissue a being a “breast affection” (abstract) or a “condition of the breast” (col. 4, ln. 37). Additionally, there is no statement or evidence in the reference that 4-hydroxy tamoxifen reduces breast density. Significantly, the reduction of class III or class IV breast density would not be inherent in a general method of treating breast conditions, because class III or class IV breast density does not characterize all breast conditions. Even if some breast conditions are characterized by class III or class IV breast density, inherency “may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (quoting *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981). Moreover, “obviousness cannot be predicated on what is unknown.” *In re Spormann*, 53 CCPA 1375, 363 F.2d 444, 448, 150 USPQ 449, 452 (CCPA 1966).

As Mauvais-Jarvis fails to teach or suggest the claimed invention, Applicant respectfully requests withdrawal of the prior art rejection.

**D. The Claims Are Patentable over the Publication of Pujol et al.**

Claims 1-12 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Pujol et al., *Cancer Chemotherapy and Pharmacology*, 36: 493-498 (1995) (“Pujol”).

According to the Office, Pujol teaches a method of percutaneously administering 4-hydroxy tamoxifen to patients with normal breast tissue and to patients with breast cancer. Because breast cancer itself comprises dense tissue, the Office asserts that Pujol inherently satisfies the limitations of the claimed invention. Applicant traverses the rejection.

Contrary to the rejection, Pujol neither teaches nor suggests the claimed invention, because breast cancer does not equate to class III or class IV breast density. In breast cancer, dense breast tissue often is limited within the discrete borders of a tumor. Class III and class IV density breasts, however, as defined by American College of Radiology standards, contain heterogeneously dense tissue or extremely dense tissue, respectively (*see* specification, paragraph 18). The claimed invention requires a patient having class III or class IV dense breast composition, so Pujol does not inherently anticipate the invention. Additionally, because Pujol lacks any indication that percutaneously administered 4-hydroxy tamoxifen reduces heterogeneous breast density, it does not render the invention obvious.

As Pujol fails to teach or suggest the claimed invention, Applicant respectfully requests withdrawal of the prior art rejection.

**E. Rejections over U.S. Application No. 10/734,638 are Merely Provisional**

Claims 1-12 were provisionally rejected (a) under the judicially created doctrine of obviousness-types double patenting as being allegedly unpatentable over claims 1-12 of U.S. Application No. 10/734,638 and (b) under 35 U.S.C. 103(a) over U.S. Application No. 10/734,638.

Because the rejections are merely provisional at this time, Applicant defers any action until an actual rejection is made.

**F. Concluding Remarks**

Applicant believes that this application is in condition for allowance, and respectfully requests favorable reconsideration of it.

If the Examiner believes that an interview would advance prosecution of the application, he is invited to contact the undersigned attorney by telephone.

The Commissioner is hereby authorized to charge any additional fees that may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extension of time is needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any extension fees to Deposit Account No. 19-0741.

Respectfully submitted,

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